

# EXHIBIT 29

## PART 5

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 15/705,172		
<b>APPLICATION AS FILED - PART I</b>							
(Column 1)		(Column 2)					
FOR	NUMBER FILED	NUMBER EXTRA					
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A					
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A					
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A					
TOTAL CLAIMS (37 CFR 1.16(j))	2	minus 20 =	*				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 =	*				
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.							
<b>APPLICATION AS AMENDED - PART II</b>							
(Column 1)		(Column 2)		(Column 3)			
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA			
	Total (37 CFR 1.16(j))	*	Minus	**	=		
	Independent (37 CFR 1.16(h))	*	Minus	***	=		
	Application Size Fee (37 CFR 1.16(s))						
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA			
	Total (37 CFR 1.16(j))	*	Minus	**	=		
	Independent (37 CFR 1.16(h))	*	Minus	***	=		
	Application Size Fee (37 CFR 1.16(s))						
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
SMALL ENTITY							
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RATE(\$)						FEE(\$)	
N/A						70	
N/A						300	
N/A						360	
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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: September 26, 2017  
Electronic Signature for Amy E. Mandragouras, Esq.: /Amy E. Mandragouras, Esq./

Docket No.: AVN-008CN41  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Stephen Donald Wilton *et al.*

Application No.: 15/705,172

Confirmation No.: 2879

Filed: September 14, 2017

Art Unit: 1674

For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF

Examiner: K. Chong

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)**

Dear Sir:

In compliance with 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the document listed on the attached PTO/SB/08. In accordance with 37 C.F.R. § 1.98(a)(2)(i)-(iv), Applicant has not included a copy of the U.S. Patent Publication.

It is respectfully requested that the document listed on the PTO/SB/08 be expressly considered by the Examiner during the prosecution of this application, and that the document be made of record therein and appear among the “References Cited” on any patent to issue therefrom.

The filing of this Information Disclosure Statement is not to be interpreted as a representation that the cited document is material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of the document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant understands the Examiner will make an independent evaluation of the cited document.

Application No.: 15/705,172

Docket No.: AVN-008CN41

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 C.F.R. § 1.97(b)(1)). Applicant believes no fee is due with this statement.

Dated: September 26, 2017

Respectfully submitted,

Electronic signature: /Amy E. Mandragouras, Esq./  
Amy E. Mandragouras, Esq.  
Registration No.: 36,207  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 217-4626  
(617) 217-4699 (Fax)  
Attorney/Agent For Applicant

Doc code: IDS

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
1						

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
1		20170009234	A1	2017-01-12	WILTON et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS							Remove	
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
1								

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS							Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.					T <sup>5</sup>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

1

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to  any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-26
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	30470917
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Amy E. Mandragouras/Anita Costa
<b>Filer Authorized By:</b>	Amy E. Mandragouras
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	26-SEP-2017
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	17:31:06
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

Submitted with Payment	no
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	2017-00-26_IDSTRANS_AVN-008CN41_4837-0227-6945_v1.pdf	24722 a2f4b83aa8b4579bae0fe7b868490637ee4 4a3f7	no	2

**Warnings:**

This is not an USPTO supplied IDS fillable form

2	Information Disclosure Statement (IDS) Form (SB08)	SB08.pdf	1058268 720550c02315856293e36d5f694fb7618ea 25b9a	no	4
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**Warnings:**

**Information:**

Total Files Size (in bytes):	1082990
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**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

**To:** chris.schlauch@nelsonmullins.com,ipqualityassuranceboston@nelsonmullins.com,ipboston.docketing@nelsonmullins.com  
**From:** PAIR\_eOfficeAction@uspto.gov  
**Cc:** PAIR\_eOfficeAction@uspto.gov  
**Subject:** Private PAIR Correspondence Notification for Customer Number 123147

Sep 26, 2017 03:40:05 AM

Dear PAIR Customer:

Nelson Mullins Riley & Scarborough LLP/Sarepta  
One Post Office Square  
Boston, MA 02109  
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 123147 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

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Application	Document	Mailroom Date	Attorney Docket No.
15705172	APP.FILE.REC	09/26/2017	AVN-008CN41

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>.

If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov with 'e-Office Action' on the subject line or call 1-866-217-9197 during the following hours:

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## UNITED STATES PATENT AND TRADEMARK OFFICE

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 Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	AVN-008CN41	2879
123147	7590	10/05/2017	EXAMINER	
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			10/05/2017	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com  
 chris.schlauch@nelsonmullins.com  
 ipqualityassuranceboston@nelsonmullins.com

<b>Office Action Summary</b>	Application No. 15/705,172	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>Period for Reply</b>			
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
<p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>09/26/2017</u>.</p> <p><input type="checkbox"/> A declaration(s)/affidavit(s) under <b>37 CFR 1.130(b)</b> was/were filed on _____.</p> <p>2a) <input type="checkbox"/> This action is <b>FINAL</b>.      2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.</p> <p>4) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>			
<b>Disposition of Claims*</b>			
<p>5) <input checked="" type="checkbox"/> Claim(s) <u>2 and 3</u> is/are pending in the application.</p> <p>5a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>6) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are rejected.</p> <p>8) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>9) <input checked="" type="checkbox"/> Claim(s) <u>2 and 3</u> are subject to restriction and/or election requirement.</p>			
<p>* If any claims have been determined <u>allowable</u>, you may be eligible to benefit from the <b>Patent Prosecution Highway</b> program at a participating intellectual property office for the corresponding application. For more information, please see <a href="http://www.uspto.gov/patents/init_events/pph/index.jsp">http://www.uspto.gov/patents/init_events/pph/index.jsp</a> or send an inquiry to <a href="mailto:PPHfeedback@uspto.gov">PPHfeedback@uspto.gov</a>.</p>			
<b>Application Papers</b>			
<p>10) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>11) <input checked="" type="checkbox"/> The drawing(s) filed on <u>09/14/2017</u> is/are: a) <input checked="" type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.</p> <p>    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</p>			
<b>Priority under 35 U.S.C. § 119</b>			
<p>12) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p>			
<b>Certified copies:</b>			
<p>a) <input type="checkbox"/> All    b) <input type="checkbox"/> Some** c) <input type="checkbox"/> None of the:</p> <p>    1. <input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p>    2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p>    3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p>			
<p>** See the attached detailed Office action for a list of the certified copies not received.</p>			
<b>Attachment(s)</b>			
<p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)     Paper No(s)/Mail Date <u>09/22/2017</u></p> <p>3) <input type="checkbox"/> Interview Summary (PTO-413)     Paper No(s)/Mail Date. _____.</p> <p>4) <input type="checkbox"/> Other: _____.</p>			

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The present application is being examined under the pre-AIA first to invent provisions.

#### **DETAILED ACTION**

##### ***Status of Application/Amendment/Claims***

Claims 2 and 3 are pending and currently under examination.

##### ***Information Disclosure Statement***

The submission of the Information Disclosure Statements on 09/22/2017 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

##### ***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (WO2004/083432 cited on IDS filed 09/22/2017) and Koenig et al. (Nature 338, 509 - 511 06 April 1989 cited on IDS filed 09/22/2017).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an antisense oligonucleotide of 20-31 bases comprising a base sequence 100% complementary to consecutive bases of exon 53 of the human dystrophin pre-mRNA, wherein the antisense oligonucleotide base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195, wherein uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense induces exon 53 skipping. The claims are further drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

van Ommen teach a genus of oligonucleotides 16-50 complementary to exon 53 and has identified an active range in the DMD gene and have shown two oligonucleotide h53AON1 and h53AON2 that cause skipping of exon 53 (see Table 2). van Ommen et al. teach the oligonucleotides can be complementary to the exon in the pre-mRNA. Thus given the sequence of the DMD gene has been identified, as demonstrated by Koenig et al., an oligonucleotide sequence complementary to that

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portion of the mRNA is exactly determined by the simple base pairing rules of DNA and RNA (G being complementary to C, and A being complementary to T (or U)).

vanOmmen et al. the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages (see claim 12 and page 23). The oligonucleotide taught by van Ommen et al. encompasses both DNA and RNA nucleic acids as well as nucleic acids that are a combination of DNA and RNA as stated on page 9: lines 9-10 "Any oligonucleotide fulfilling the requirements of the invention may be used to induce exon skipping in the DMD gene." van Ommen et al. teach different nucleic acids may be used to generate the oligonucleotide (see page 9 line 30 - page 10). Thus oligonucleotides in which uracil bases are thymine bases are encompassed in the meaning of 'oligonucleotide' taught by van Ommen et al.

It would have been obvious to one of ordinary skill in the art to make an antisense oligonucleotide of 20-31 bases comprising at least 12 bases of SEQ ID No. 195. Given van Ommen et al. teach a genus of oligonucleotides of up to 50 nucleotides in length, one of skill in the art would have been motivated to use the sequence of h53AON1 to arrive at oligonucleotides of 20 nucleotides and having 12 nucleotides of SEQ ID No. 195 (which overlaps with 3 nucleotides of h53AON1). Because van Ommen et al. has identified exon 53 and shown oligonucleotides targeting this region can cause exon skipping and because the mRNA sequence containing the exon 53 was known in the prior art, as shown by Keonig et al., the combination of these teachings

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provides motivation to prepare obvious variants of h53AON1 to try and optimize the activity of the oligonucleotide to prepare the most effective therapeutic for treating DMD.

It would have been routine and a common strategy to try and enhance the oligonucleotide by identifying variants of that oligonucleotide that have a higher level of activity and a common and efficient strategy for doing so is to synthesize and test longer oligonucleotides containing within them the sequence known to have the desired activity.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP §

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717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit [www.uspto.gov/forms/](http://www.uspto.gov/forms/). The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to

<http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to antisense oligonucleotides having at least 17 consecutive bases of SEQ ID No. 193.

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the instant claims and the claims of the patent are drawn to antisense oligonucleotides having at least 17 consecutive bases of SEQ ID No. 193.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

#### **706.07(a) Final Rejection, When Proper on Second Action [R-07.2015]**

Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). Where information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP § 609.04(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong whose telephone number is 571-272-3111**. The examiner can normally be reached Monday thru Friday 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Ram Shukla at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

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folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
Art Unit 1674



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/857,555	09/17/2015	Stephen Donald Wilton	AVN-008CN31	6627
123147	7590	11/06/2015	EXAMINER	
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			11/06/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com  
 chris.schlauch@nelsonmullins.com  
 ipqualityassuranceboston@nelsonmullins.com

<b>Office Action Summary</b>	Application No. <b>14/857,555</b>	Applicant(s) <b>WILTON ET AL.</b>	
	Examiner <b>KIMBERLY CHONG</b>	Art Unit <b>1674</b>	AIA (First Inventor to File) Status <b>No</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on 09/21/2015.  
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.

4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims\***

5)  Claim(s) 21-24 is/are pending in the application.  
 5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

6)  Claim(s) \_\_\_\_\_ is/are allowed.

7)  Claim(s) 21-24 is/are rejected.

8)  Claim(s) \_\_\_\_\_ is/are objected to.

9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

10)  The specification is objected to by the Examiner.

11)  The drawing(s) filed on 09/17/2015 is/are: a)  accepted or b)  objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

a)  All    b)  Some\*\* c)  None of the:  
 1.  Certified copies of the priority documents have been received.  
 2.  Certified copies of the priority documents have been received in Application No. 11/570,691.  
 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)

2)  Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
 Paper No(s)/Mail Date 9/18/15, 9/21/15, 10/15/15.

3)  Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.

4)  Other: \_\_\_\_\_.

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The present application is being examined under the pre-AIA first to invent provisions.

## **DETAILED ACTION**

### ***Status of Application***

Claims 21-24 are pending and currently under examination. SEQ ID No. 207 is free of the prior art searched.

### ***Information Disclosure Statement***

The submission of the Information Disclosure Statements on 09/18/2015, 09/21/2015 and 10/15/2015 is in compliance with 37 CFR 1.97. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

The information disclosure statements filed on 09/18/2015 having 8 pages fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because of the following reasons: The NPL documents having numbers 12 and 13 contained in the information disclosure statement filed 09/18/2015 have not been considered because the documents do not have the required date listed. The remaining documents have been considered and a signed copy has been placed in the file.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-22 of Application No. 14/857,561. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 8,524,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

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If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
Art Unit 1674

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: September 22, 2017  
Electronic Signature for Amy E. Mandragouras, Esq.: /Amy E. Mandragouras, Esq./

Docket No.: AVN-008CN41  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Stephen Donald Wilton *et al.*

Application No.: 15/705,172

Confirmation No.: 2879

Filed: September 14, 2017

Art Unit: 1674

For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF

Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached PTO/SB/08. It is respectfully requested that the documents listed on the PTO/SB/08 be expressly considered by the Examiner during the prosecution of this application, and that the documents be made of record therein and appear among the “References Cited” on any patent to issue therefrom.

For the Examiner's convenience in reviewing this continuation application, Applicant submits a consolidated PTO/SB/08, listing all references cited during the prosecution of the parent applications. The present application is a continuation of U.S. Application No. 15/274,772, filed September 23, 2016 (Atty. Docket No. AVN-008CN37). In accordance with 37 C.F.R. §1.98(d), copies of the references previously cited by or submitted to the Office in the parent applications are not enclosed, but will be provided upon request.

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

Applicant calls to the attention of the Examiner the following Applications and Office Actions issued therein:

<b>Applications</b>				
<i>Examiner's Initials</i>	<i>Serial No.</i>	<i>Filing Date</i>	<i>First Named Inventor</i>	<i>Docket No.</i>
	11/570,691	January 15, 2008	Stephen Donald Wilton	AVN-008
	12/837,356	July 15, 2010	Stephen Donald Wilton	AVN-008CN
	12/837,359	July 15, 2010	Stephen Donald Wilton	AVN-008CN2
	12/860,078	August 20, 2010	Stephen Donald Wilton	AVN-008CN3
	13/168,857	June 24, 2011	Stephen Donald Wilton	AVN-008CN4
	13/168,863	June 24, 2011	Stephen Donald Wilton	AVN-008CN5
	13/270,500	October 11, 2011	Stephen Donald Wilton	AVN-008CN6
	13/270,531	October 11, 2011	Stephen Donald Wilton	AVN-008CN7
	13/270,744	October 11, 2011	Stephen Donald Wilton	AVN-008CN8
	13/270,937	October 11, 2011	Stephen Donald Wilton	AVN-008CN9
	13/270,992	October 11, 2011	Stephen Donald Wilton	AVN-008CN10
	13/271,080	October 11, 2011	Stephen Donald Wilton	AVN-008CN11
	13/727,415	December 26, 2012	Stephen Donald Wilton	AVN-008CN12
	13/741,150	January 14, 2013	Stephen Donald Wilton	AVN-008CN13
	13/826,613	March 14, 2013	Stephen Donald Wilton	AVN-008CN14
	13/826,880	March 14, 2013	Stephen Donald Wilton	AVN-008CN15
	13/902,376	May 24, 2013	Stephen Donald Wilton	AVN-008CN17
	13/963,578	August 9, 2013	Stephen Donald Wilton	AVN-008CN18

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Docket No.: AVN-008CN41

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	14/857,569	September 17, 2015	Peter SAZANI	AVN-009DVCN3
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	14/743,856	June 18, 2015	R.K. BESTWICK	AVN-10PCCN
	14/213,629	March 14, 2014	E.M. KAYE	AVN-012ARCE
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	13/509,331	July 9, 2012	S.D. WILTON	AVN-015US
	14/108,137	December 16, 2013	S.D. WILTON	AVN-015USCN
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	14/213,641	March 14, 2014	R.K. BESTWICK	AVN-017RCE
	14/776,533	September 14, 2015	R.K. BESTWICK	AVN-017CPUS

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Examiner's Initials	Serial No.	Date Mailed from USPTO	Examiner
	11/570,691	August 16, 2010	Kimberly Chong
	11/570,691	March 15, 2010	Kimberly Chong
	11/570,691	May 26, 2009	Kimberly Chong
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	12/837,359	March 12, 2012	Kimberly Chong
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Docket No.: AVN-008CN41

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	13/270,500	July 30, 2012	Kimberly Chong
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Docket No.: AVN-008CN41

	14/316,609	March 16, 2015	Kimberly Chong
	14/316,609	October 21, 2014	Kimberly Chong
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	12/605,276	June 18, 2014	J. McDonald
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	13/830,253	June 11, 2014	J. McDonald
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	14/523,610	May 11, 2016	J. McDonald
	14/852,257	October 27, 2015	J. McDonald
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	14/852,264	April 21, 2016	J. McDonald
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	14/214,567	July 7, 2016	E. Poliakova-Georgan
	14/214,567	December 3, 2015	E. Poliakova-Georgan
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	14/213,607	September 15, 2015	D.H. Shin

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	14/213,607	April 1, 2015	D.H. Shin
	14/213,607	September 18, 2014	D.H. Shin
	14/214,480	August 2, 2016	D.H. Shin
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	14/213,641	August 1, 2016	D.H. Shin
	14/213,641	October 16, 2015	D.H. Shin
	14/213,641	March 31, 2015	D.H. Shin
	14/213,641	September 18, 2014	D.H. Shin
	14/213,629	May 23, 2016	E. Poliakova-Georgan
	14/213,629	August 21, 2015	E. Poliakova-Georgan
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	14/743,856	August 1, 2016	A. Hudson Bowman
	14/776,533	February 28, 2017	D. Shin
	14/776,533	August 3, 2016	D. Shin
	15/274,719	December 16, 2016	K. Chong
	15/274,772	December 30, 2016	K. Chong
	15/274,772	September 18, 2017	K. Chong

The Examiner is requested to review the file histories of these applications, including cited references, Office Actions, Responses, etc., and is asked to contact Applicant's Attorney if the Examiner would like the Applicant to supply copies of any or all of the information included in any of these applications. For any of these applications, if Applicant's Attorney is not contacted by the Examiner with such a request, then it will be concluded that the Examiner has reviewed or will review the file content of these applications.

Applicant respectfully requests that the Examiner initial the blank columns next to the cited Applications and Office Actions, to indicate that the information has been considered by the Examiner. Alternatively, Applicant requests that the Examiner insert the phrase, "All references

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The filing of this Information Disclosure Statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any documents herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant understands the Examiner will make an independent evaluation of the cited documents.

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 C.F.R. § 1.97(b)(1)). Applicant believes no fee is due with this statement.

Dated: September 22, 2017

Respectfully submitted,

Electronic signature: /Amy E. Mandragouras, Esq./  
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Attorney/Agent For Applicant

Doc code: IDS

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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1	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of 8036 Cells, Pages 2, Exhibit Number 1179 filed in Interferences 106,007 and 106,008 on February 16, 2015.
2	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1178 filed in Interferences 106,007 and 106,008 on February 16, 2015.
3	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of 8036 Cells, Pages 1, Exhibit Number 1172 filed in Interferences 106,007 and 106,008 on February 16, 2015.
4	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.
5	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.
6	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.
7	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.
8	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
10	Laboratory Notebook Entry: General RNA recovery, Pages 2, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.
11	Laboratory Notebook Entry: Lab-on-a-Chip Analysis, Pages 3, Exhibit Number 1184 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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13	Letter from the FDA to Sarepta Therapeutics, Inc., Re: ACCELERATED APPROVAL for the use of Exondys 51 (eteplirsen), FDA Reference ID: 3987286, dated September 19, 2016, 11 pages.
14	Letter to the U.S. Food and Drug Administration, (Dr. Billy Dunn, M.D. Director Division of Neurology Products, Office of Drug Evaluation 1, Center for Drug Evaluation and Research), for The Peripheral and Central Nervous System Advisory Committee Meeting (AdComm) supporting approval of eteplirsen, dated February 24, 2016, 4 pages.
15	Letter to the U.S. Food and Drug Administration, (Dr. Janet Woodcock, M.D. Director, CDER), from The Congress of The United States regarding Duchenne muscular dystrophy, dated February 17, 2016, 7 pages.
16	List of Publications for Matthew J. A. Wood, M.D., D. PHIL., 11 pages, (Exhibit Number 2124 filed in interferences 106,007 and 106,008 on February 17, 2015).
17	LIU, Hong-Xiang et al., "Identification of functional exonic splicing enhancer motifs recognized by individual SR proteins," Genes & Development, Vol. 12:1998-2012 (1998)
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23	MANN, Christopher J. et al., "Improved antisense oligonucleotide induced exon skipping in the mdx mouse model of muscular dystrophy," <i>The Journal of Gene Medicine</i> , Vol. 4:644-654 (2002)
24	MANNINO, Raphael J. et al., "Liposome Mediated Gene Transfer," <i>BioTechniques</i> , Vol. 6(7):682-690 (1988)
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26	Manzur A, et al., "Glucocorticoid corticosteroids for Duchenne muscular dystrophy," <i>Cochrane Database Syst Rev</i> . 2004;(2):CD003725.
27	MARSHALL, N.B. et al., "Arginine-rich cell-penetrating peptides facilitate delivery of antisense oligomers into murine leukocytes and alter pre-mRNA splicing," <i>Journal of Immunological Methods</i> , Vol. 325:114-126 (2007)
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31	MATSUO, Masafumi et al., "Treatment of Duchenne Muscular Dystrophy with Oligonucleotides against an Exonic Splicing Enhancer Sequence," <i>Basic Appl. Myol.</i> , Vol. 13(6):281-285 (2003)
32	MATSUO, Masafumi, "Duchenne and Becker Muscular Dystrophy: From Gene Diagnosis to Molecular Therapy," <i>IUBMB Life</i> , Vol. 53:147-152 (2002)
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First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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35	Mazzone E, et al. "Functional changes in Duchenne muscular dystrophy: a 12-month longitudinal cohort study," Neurology 2011;77(3):250-6.
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37	MCCLOREY, G. et al., "Antisense oligonucleotide-induced exon skipping restores dystrophin expression in vitro in a canine model of DMD," Gene Therapy, Vol. 13:1373-1381 (2006)
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39	MCCLOREY, Graham et al., "Splicing intervention for Duchenne muscular dystrophy," Current Opinion in Pharmacology, Vol. 5:529-534 (2005)
40	McDonald CM, et al., "Profiles of Neuromuscular Diseases, Duchenne muscular dystrophy," Am J Phys Med Rehabil 1995;74:S70-S92
41	McDonald CM, et al., "The 6-minute walk test as a new outcome measure in Duchenne muscular dystrophy," Muscle Nerve 2010;41:500-10.
42	McDonald CM, et al., "The 6-minute walk test in Duchenne/Becker muscular dystrophy: longitudinal observations," Muscle Nerve 2010;42: 966-74.
43	Mendell JR et al., "Evidence-based path to newborn screening for Duchenne muscular Dystrophy," Ann Neurol 2012;71:304-13.
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First Named Inventor	Stephen Donald WILTON
Art Unit	1674
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Attorney Docket Number	AVN-008CN41

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46	MENDELL, Jerry R. et al., "Eteplirsen for the Treatment of Duchenne Muscular Dystrophy," Ann. Neurol., Vol. 74:637-647 (2013) (Exhibit Number 2058 filed in interferences 106008, 106013, 106007 on November 18, 2014)
47	MENDELL, Jerry R. et al., "Eteplirsen in Duchenne Muscular Dystrophy (DMD): 144 Week Update on Six-Minute Walk Test (6MWT) and Safety," slideshow, presented at the 19th International Congress of the World Muscle Society, 17 pages (2014) (Exhibit Number 2059 filed in interferences 106008, 106013, 106007 on November 18, 2014)
48	MENDELL, Jerry R. et al., "Gene therapy for muscular dystrophy: Lessons learned and path forward," Neuroscience Letters, Vol. 527:90-99 (2012)
49	Merlini L, et al., "Early corticosteroid treatment in 4 Duchenne muscular dystrophy patients: 14-year follow-up," Muscle Nerve 2012;45:796-802.
50	Mfold illustrations for Exon 51 and Exon 53 with varying amounts of intron sequence, (University of Western Australia Exhibit 2132, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).

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( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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1	Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Briefing Document, NDA 206488, 186 pages.
2	Sarepta Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 133 pages
3	Sarepta Press Release, Sarepta Issues Statement on Advisory Committee Outcome for Use of Eteplirsen in the Treatment of Duchenne Muscular Dystrophy, April 25, 2016, 2 pages
4	Sarepta Therapeutics Press Release, dated January 12, 2015, Exhibit Number 1119 filed in interferences 106,007 and 106,008 on February 17, 2015.
5	Sarepta Therapeutics, Advisory Committee Briefing Materials: Available for Public Release, "Peripheral and Central Nervous System Drugs Advisory Committee," Eteplirsen Briefing Document Addendum, NDA 206488, pages 1-9, dated January 22, 2016.
6	Sarepta Therapeutics, Advisory Committee Briefing Materials: Available for Public Release, "Peripheral and Central Nervous System Drugs Advisory Committee," Eteplirsen Briefing Document, NDA 206488, pages 1-166, dated January 22, 2016.
7	Sarepta Therapeutics, Inc. News Release, "Sarepta Therapeutics Announces FDA Accelerated Approval of EXONDYS 51™ (eteplirsen) injection, an Exon Skipping Therapy to Treat Duchenne Muscular Dystrophy (DMD) Patients Amenable to Skipping Exon 51," September 19, 2016, 2 pages.
8	Sarepta, "AVI BioPharma Initiates Dosing in Phase 2 Study of Eteplirsen in Duchenne Muscular Dystrophy Patients," press release, 4 pages, dated August 15, 2011 (Exhibit Number 2082 filed in interferences 106008, 106013, 106007 on November 18, 2014)
9	Sarepta, "Sarepta Therapeutics Announces Eteplirsen Demonstrates Continued Stability on Walking Test through 120 Weeks in Phase IIb Study in Duchenne Muscular Dystrophy," press release, 3 pages, dated January 15, 2014 (Exhibit Number 2034 filed in interferences 106008, 106013, 106007 on November 18, 2014)
10	Sarepta, "Sarepta Therapeutics Reports Long-Term Outcomes through 144 Weeks from Phase IIb Study of Eteplirsen in Duchenne Muscular Dystrophy," press release, <a href="http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&amp;p=irol-newsArticle&amp;id=1946426">http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&amp;p=irol-newsArticle&amp;id=1946426</a> , 4 pages, dated July 10, 2014
11	Scully, Michele et al., "Review of Phase II and Phase III Clinical Trials for Duchenne Muscular Dystrophy", Expert Opinion on Orphan Drugs, Vol.1(1):33-46 (2013)

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12	Second Preliminary Amendment filed in US Application No. 13/550,210, 5 pages, dated January 3, 2013 (Exhibit Number 2062 filed in interferences 106008, 106013, 106007 on November 18, 2014)
13	Second Written Opinion for Application No. PCT/AU2010/001520, 7 pages, dated October 13, 2011
14	Semi Quantitative Lab-on-Chip Analysis of Second PCR Product, Pages 1, Exhibit Number 1183 filed in Interferences 106,007 and 106,008 on February 16, 2015.
15	Sequence Listing - Serial No. 13/550,210, as filed July 16, 2012 (9 pages), Exhibit Number 1205 filed in Interferences 106,007 and 106,008 on February 17, 2015.
16	Sequence of Exon 46 of Dystrophin Gene, 1 page
17	Sequence of Exon 51 of Dystrophin Gene, 1 page
18	Shabanpoor et al., "Bi-specific splice-switching PMO oligonucleotides conjugated via a single peptide active in a mouse model of Duchenne muscular dystrophy," Nucleic Acids Res., pp. 1-11 (December, 2014), Exhibit Number 1114 filed in interferences 106,007 and 106,008 on February 17, 2015.
19	SHAPIRO, Marvin B. et al., "RNA splice junctions of different classes of eukaryotes: sequence statistics and functional implications in gene expression," Nucleic Acids Research, Vol. 15(17):7155-7174 (1987)
20	SHERRATT, Tim G. et al., "Exon Skipping and Translation in Patients with Frameshift Deletions in the Dystrophin Gene," Am. J. Hum. Genet., Vol. 53:1007-1015 (1993)
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22	SHIMIZU, Miho et al., "Oligo(2'-O-methyl)ribonucleotides Effective probes for duplex DNA," FEBS Letters, Vol. 302 (2):155-158 (1992) (Exhibit Number 1035 filed in interferences 106008, 106007 on November 18, 2014)

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23	Siemens Healthcare Diagnostics, Inc. v. Enzo Life Sciences, Inc., 2013 WL 4411227, *11 [Parallel cite: U.S.D.C., D. Mass., Civil No. 10-40124-FDS], Decided Aug. 14, 2013 (12 pages); [Cited as: 2013 WL 4411227], Exhibit Number 1210 filed in Interferences 106,007 and 106,008 on February 17, 2015.
24	SIERAKOWSKA, Halina et al., "Repair of thalassemic human beta-globin mRNA in mammalian cells by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 93:12840-12844 (1996)
25	Sontheimer et al., "Metal ion catalysis during group II intron self-splicing: parallels with the spliceosome," Genes & Development, Vol. 13, pp. 1729-1741 (1999), Exhibit Number 1195 filed in Interferences 106,007 and 106,008 on February 17, 2015.
26	Sontheimer et al., "Three Novel Functional Variants of Human U5 Small Nuclear RNA," Vol. 12, No. 2, pp. 734-746 (Feb., 1992), Exhibit Number 1194 filed in Interferences 106,007 and 106,008 on February 17, 2015.
27	SONTHEIMER, Erik J. et al., "Metal ion catalysis during splicing of pre-messenger RNA," Nature, Vol. 388:801-805 (1997) (Exhibit Number 1036 filed in Interferences 106,008, 106,007 on November 18, 2014)
28	SONTHEIMER, Erik J. et al., "The U5 and U6 Small Nuclear RNAs as Active Site Components of the Spliceosome," Science, Vol. 262:1989-1997 (1993) (Exhibit Number 1058 filed in Interferences 106,008, 106,007 on November 18, 2014)
29	Standard Operating Procedure FPLC Desalting, Pages 6, Exhibit Number 1144 filed in Interferences 106,007 and 106,008 on February 16, 2015.
30	Stanton, Robert et al., "Chemical Modification Study of Antisense Gapmers", Nucleic Acid Therapeutics, Vol. 22(5): 344-359 (2012)
31	Statement On A Nonproprietary Name Adopted By the USAN Council, ETEPLIRSEN, Chemical Structure, 2010, pages 1-5.
32	STEIN, CA, "Delivery of antisense oligonucleotides to cells: a consideration of some of the barriers," Monographic supplement series: Oligos & Peptides - Chimica Oggi - Chemistry Today, Vol. 32(2):4-7 (2014) (Exhibit Number 2022 filed in Interferences 106,008, 106,013, 106,007 on November 18, 2014)
33	STEIN, Cy A. et al., "Therapeutic Oligonucleotides: The Road Not Taken," Clin. Cancer Res., Vol. 17(20):6369-6372 (2011) (Exhibit Number 2026 filed in Interferences 106,008, 106,013, 106,007 on November 18, 2014)

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34	STEIN, David et al., "A Specificity Comparison of Four Antisense Types: Morpholino, 2'-O-Methyl RNA, DNA, and Phosphorothioate DNA," <i>Antisense &amp; Nucleic Acid Drug Development</i> , Vol. 7:151-157 (1997)
35	Strober JB, "Therapeutics in Duchenne muscular dystrophy," <i>NeuroRX</i> 2006; 3:225-34.
36	Summary of Professional Experience (Dr. Erik J. Sontheimer), Pages 4, Exhibit Number 1223 filed in Interferences 106,007 and 106,008 on February 17, 2015.
37	SUMMERTON, James et al., "Morpholino and Phosphorothioate Antisense Oligomers Compared in Cell-Free and In-Cell Systems," <i>Antisense &amp; Nucleic Acid Drug Development</i> , Vol. 7:63-70 (1997)
38	SUMMERTON, James et al., "Morpholino Antisense Oligomers: Design, Preparation, and Properties," <i>Antisense &amp; Nucleic Acid Drug Development</i> , Vol. 7:187-195 (1997)
39	SUMMERTON, James, "Morpholino antisense oligomers: the case for an RNase H-independent structural type," <i>Biochimica et Biophysica Acta</i> , Vol. 1489:141-158 (1999) (Exhibit Number 1038 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
40	Supplementary European Search Report for Application No. 10829367.1, 8 pages, dated May 22, 2013
41	Suter et al., "Double-target antisense U7 snRNAs promote efficient skipping of an aberrant exon in three human Beta-thalassemic mutations," 8:13 <i>HUMAN MOLECULAR GENETICS</i> 2415-2423 (1999) (Exhibit Number 1083 filed in Interferences 106008, 106007 on December 23, 2014)
42	T HOEN, Peter A.C. et al., "Generation and Characterization of Transgenic Mice with the Full-length Human DMD Gene," <i>The Journal of Biological Chemistry</i> , Vol. 283(9):5899-5907 (2008) Exhibit Number 2030 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
43	Table 1: Primer and Product Details for Exon 51 and 53 Reports on AONs of 20 to 50 Nucleotides dd 07 JAN 2015, Pages 1, Exhibit Number 1177 filed in Interferences 106,007 and 106,008 on February 16, 2015.
44	Takeshima et al., "Oligonucleotides against a splicing enhancer sequence led to dystrophin production in muscle cells from a Duchenne muscular dystrophy patient," <i>Brain &amp; Dev.</i> , Vol. 23, pp. 788-790 (2001), Exhibit Number 1196 filed in Interferences 106,007 and 106,008 on February 17, 2015.

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45	TAKESHIMA, Yasuhiro et al., "Modulation of In Vitro Splicing of the Upstream Intron by Modifying an Intra-Exon Sequence Which Is Deleted from the Dystrophin Gene in Dystrophin Kobe," J. Clin. Invest., Vol. 95:515-520 (1995)
46	TANAKA, Kenji et al., "Polypurine Sequences within a Downstream Exon Function as a Splicing Enhancer," Molecular and Cellular Biology, Vol. 14(2):1347-1354 (1994)
47	Telios Pharm., Inc. v. Merck KgaA, No. 96-1307, 1998 WL 35272018 (S.D. Cal. Nov. 18, 1998), 11 pages (Exhibit Number 2153 filed in interference 106013 on October 29, 2015)
48	THANH, Le Htiet et al., "Characterization of Revertant Muscle Fibers in Duchenne Muscular Dystrophy, Using Exon-Specific Monoclonal Antibodies against Dystrophin," Am. J. Hum. Genet., Vol. 56:725-731 (1995)
49	The Regents of the University of California v. Dako North America, Inc., U.S.D.C., N.D. California, No. C05-03955 MHP, April 22, 2009 (2009 WL 1083446 (N.D.Cal.), Exhibit Number 1206 filed in Interferences 106,007 and 106,008 on February 17, 2015.
50	TIAN, Xiaobing et al., "Imaging Oncogene Expression," Ann. N.Y. Acad. Sci., Vol. 1002:165-188 (2003) (Exhibit Number 2029 filed in interferences 106008, 106013, 106007 on November 18, 2014)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	Transcript of 2nd Deposition of Erik J. Sontheimer, Ph.D., dated March 12, 2015, (Academisch Ziekenhuis Leiden Exhibit 1231, filed April 3, 2015 in Interference 106007 and 106008, pages 1-185).
2	Transcript of 2nd Deposition of Matthew J.A. Wood, M.D., D. Phil, dated March 5, 2015, (Academisch Ziekenhuis Leiden Exhibit 1230, filed April 3, 2015 in Interference 106007 and 106008, pages 1-117).
3	Transcript of December 12, 2014 Teleconference with Administrative Patent Judge Schafer (rough draft) (previously filed in Int. No. 106,008 as Ex. 2114), Pages 28 Exhibit Number 1001 filed in Interference 106,013 on February 17, 2015.
4	Transcript of the January 21, 2015 deposition of Erik Sontheimer, Ph.D., Patent Interference Nos. 106,007 and 106,008, 98 pages, dated January 21, 2015 (Exhibit Number 2122 filed in interferences 106,007 and 106,008 on February 17, 2015).
5	Transcript of the March 11, 2015 deposition of Judith van Deutekom, Ph.D., (University of Western Australia Exhibit 2141, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-168).
6	Transcript of the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2142, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-183).
7	Transcript of the March 5, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., (University of Western Australia Exhibit 2146, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-115).
8	Transfection of AON, Pages 1, Exhibit Number 1170 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	U.S. Food and Drug Administration Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 178 pages.
10	U.S. Food and Drug Administration Statement, dated December 30, 2014 (2 pages), Exhibit Number 1204 filed in Interferences 106,007 and 106,008 on February 17, 2015.
11	U.S. Patent Application No. 12/198,007, as-filed August 25, 2008 ("the '007 Application") (Exhibit Number 1073 filed in Interferences 106008, 106007 on December 23, 2014)

Application Number

36740

15705172

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2017-09-14

First Named Inventor

Stephen Donald WILTON

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12		U.S. Patent Application No. 12/976,381, as-filed December 22, 2010 ("the '381 Application") (Exhibit Number 1074 filed in interferences 106008, 106007 on December 23, 2014)
13		U.S. Patent Application Publication No. 2001/0056077 ("Matsuo") (Exhibit Number 1080 filed in interferences 106008, 106007 on December 23, 2014)
14		U.S. Patent Application Publication No. 2002/0049173 ("Bennett et al.") (Exhibit Number 1081 filed in interferences 106008, 106007 on December 23, 2014)
15		U.S. Patent No. 5,190,931 ("the '931 Patent") (Exhibit Number 1069 filed in interferences 106008, 106007 on December 23, 2014)
16		U.S. Patent No. 7,001,761 (the "Xiao" Patent) (Exhibit Number 1070 filed in interferences 106008, 106007 on December 23, 2014)
17		University of Western Australia Objections to Opposition Evidence, served on February 24, 2015 filed in Interference No. 106,007, Exhibit 2150, filed April 10, 2015 in Interference Nos. 106007 and 106008, pages 1-15.
18		University of Western Australia Objections to Opposition Evidence, served on February 24, 2015, filed in Interference No. 106,008, Exhibit 2151, filed April 10, 2015, in Interference Nos. 106007and 106008, pages 1-15.
19		University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 C.F.R. § 41.125(a), filed in Patent Interference No. 106008, September 20, 2016, pages 1-20 (Doc 480)
20		University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a) (Substitute), filed in Patent Interference No. 106007, May 12, 2016, pages 1-53 (Doc 476)
21		University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 C.F.R. § 41.127 filed in Patent Interference No. 106008, September 20, 2016, pages 1-3 (Doc 481)
22		University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 CFR § 41.127, filed in Patent Interference No. 106007, April 29, 2016, pages 1-3 (Doc 474)

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23	European Response, Application No. 13160338.3, 4 pages, dated June 26, 2014 (Exhibit Number 2085 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
24	University of Western Australia v. Academisch Ziekenhuis Leiden, Redeclaration - 37 CFR 41.203(c), filed in Patent Interference No. 106007, April 29, 2016, pages 1-2 (Doc 473)
25	University of Western Australia v. Academisch Ziekenhuis Leiden, Withdrawal and Reissue of Decision on Motions, filed in Patent Interference No. 106007, May 12, 2016, pages 1-2 (Doc 475)
26	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,007, April 3, 2015, pages 1-18, (Doc 423).
27	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,008, April 3, 2015, pages 1-18 (Doc 435).
28	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,007, (Doc 391), dated February 17, 2015.
29	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,008, (Doc 398), dated February 17, 2015.
30	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 3 pages, Patent Interference No. 106,013, (Doc 147), dated February 17, 2015.
31	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,007 (Doc 414), dated March 9, 2015.
32	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,008 (Doc 422), dated March 9, 2015.
33	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 83 pages, Patent Interference No. 106,008, (Doc 400), dated February 17, 2015

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34	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 93 pages, Patent Interference No. 106,007, (Doc 392), dated February 17, 2015
35	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (Standing Order ¶ 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,013, (Doc 148), dated February 17, 2015
36	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 31 pages, Patent Interference No. 106,007, (Doc 396), dated February 17, 2015
37	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 32 pages, Patent Interference No. 106,008, (Doc 401), dated February 17, 2015
38	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (35 U.S.C. §135(b)), 44 pages, Patent Interference No. 106,008, (Doc 397), dated February 17, 2015
39	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (Standing Order § 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,007, (Doc 389), dated February 17, 2015.
40	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 431).
41	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 424).
42	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-11(Doc 425).
43	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-12 (Doc 432).
44	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-12 (Doc 426).

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Attorney Docket Number	AVN-008CN41

45	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-13 (Doc 433).
46	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 427).
47	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 434).
48	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-3 (Doc 454).
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-3 (Doc 462).
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 57 pages, Patent Interference No. 106,008, (Doc 245), dated December 23, 2014.

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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1	Valorization Memorandum published by the Dutch Federation of University Medical Centers in March 2009, (University of Western Australia Exhibit 2140, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-33).
2	VAN DEUTEKOM et al., "Antisense-induced exon skipping restores dystrophin expression in DMD patient derived muscle cells," HUMAN MOLECULAR GENETICS Vol. 10, No. 15: 1547-1554 (2001) (Exhibit Number 1084 filed in Interferences 106008, 106007 on December 23, 2014)
3	van Deutekom et al., "Local Dystrophin Restoration with Antisense Oligonucleotide PRO051," N. Engl. J. Med., Vol. 357, No. 26, pp. 2677-2686 (December, 2007), Exhibit Number 1213 filed in Interferences 106,007 and 106,008 on February 17, 2015.
4	VAN DEUTEKOM, Judith C. T. et al., "Advances in Duchenne Muscular Dystrophy Gene Therapy," Nature Reviews Genetics, Vol. 4(10):774-783 (2003)
5	Van Ommen 2002 PCT (WO 02/24906 A1), 43 pages,(Exhibit Number 1071 filed in interferences 106008, 106007 on December 23, 2014)
6	van Putten M, et al., "The Effects of Low Levels of Dystrophin on Mouse Muscle Function and Pathology. PLoS ONE 2012;7:e31937, 13 pages
7	Van Vliet, Laura et al., "Assessment of the Feasibility of Exon 45-55 Multiexon Skipping for Duchenne Muscular Dystrophy", BMC Medical Genetics, Vol.9(1):105 (2008)
8	VERMA, Sandeep et al., "Modified Oligonucleotides: Synthesis and Strategy for Users," Annu. Rev. Biochem., Vol. 67:99-134 (1998) (Exhibit Number 1040 filed in interferences 106008, 106007 on November 18, 2014)
9	Mikase Corp. v. Am. Nat'l. Can Co., No. 93-7651, 1996 WL 377054 (N.D. Ill. July 1, 1996), 3 pages (Exhibit Number 2152 filed in interference 106013 on October 29, 2015)
10	VOIT, Thomas et al., "Safety and efficacy of drisapersen for the treatment of Duchenne muscular dystrophy (DEMAND II): an exploratory randomised, placebo-controlled phase 2 study," Lancet Neurol., Vol. 13:987-996 (2014) (Exhibit Number 2037 filed in interferences 106008, 106013, 106007 on November 18, 2014)
11	VOLLOCH, Vladimir et al., "Inhibition of Pre-mRNA Splicing by Antisense RNA in Vitro: Effect of RNA Containing Sequences Complementary to Exons," Biochemical and Biophysical Research Communications, Vol. 179 (3):1593-1599 (1991)

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12	Wahlestedt et al., "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," PNAS, Vol. 97, No. 10, pp. 5633-5638 (May, 2000), Exhibit Number 1201 filed in Interferences 106,007 and 106,008 on February 17, 2015.
13	Wang et al., "In Vitro evaluation of novel antisense oligonucleotides is predictive of in vivo exon skipping activity for Duchenne muscular dystrophy," J. Gene Medicine, Vol. 12, pp. 354-364 (March, 2010), Exhibit Number 1115 filed in Interferences 106,007 and 106,008 on February 17, 2015.
14	WANG, Chen-Yen et al., "pH-sensitive immunoliposomes mediate target-cell-specific delivery and controlled expression of a foreign gene in mouse," Proc. Natl. Acad. Sci. USA, Vol. 84:7851-7855 (1987)
15	WATAKABE, Akiya et al., "The role of exon sequences in splice site selection," Genes & Development, Vol. 7:407-418 (1993)
16	Watanabe et al., "Plasma Protein Binding of an Antisense Oligonucleotide Targeting Human ICAM-1 (ISIS 2302)," Oligonucleotides, Vol. 16, pp. 169- 180 (2006), Exhibit Number 1197 filed in Interferences 106,007 and 106,008 on February 17, 2015.
17	WHO Drug Information, International Nonproprietary Names for Pharmaceutical Substances (INN), Proposed INN: List 115, "CASIMERSEN," vol. 30(2): 3 pages (2016)
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19	WIJNAENDTS, L.C.D. et al., "Prognostic importance of DNA flow cytometric variables in rhabdomyosarcomas," J. Clin. Pathol., Vol. 46:948-952 (1993) (Exhibit Number 1041 filed in interferences 106008, 106007 on November 18, 2014)
20	Wilton et al. (2007) "Antisense Oligonucleotide-induced Exon Skipping Across the Human Dystrophin Gene Transcript," Molecular Therapy 15(7):1288-1296, 10 pages, (Exhibit Number 2121 filed in interferences 106,007 and 106,008 on February 17, 2015)
21	WILTON, Stephen D. et al., "Antisense oligonucleotides in the treatment of Duchenne muscular dystrophy: where are we now?" Neuromuscular Disorders, Vol. 15:399-402 (2005)
22	WILTON, Stephen D. et al., "Specific removal of the nonsense mutation from the mdx dystrophin mRNA using antisense oligonucleotides," Neuromuscular Disorders, Vol. 9:330-338 (1999)

Application Number	15705172 36749
Filing Date	2017-09-14
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Attorney Docket Number	AVN-008CN41

23	WO 2002/24906 A1 of AZL, (University of Western Australia Exhibit 2134, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-43.)
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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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- any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

- A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08a (03-15)

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STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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( Not for submission under 37 CFR 1.99)

Application Number <u>#. 30787</u>	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	MITRPANT, Chalermchai et al., "Rational Design of Antisense Oligomers to Induce Dystrophin Exon Skipping," Molecular Therapy, Vol. 17(8):1418-1426 (2009)
2	MONACO, Anthony P. et al., "An Explanation for the Phenotypic Differences between Patients Bearing Partial Deletions of the DMD Locus," Genomics, Vol. 2:90-95 (1988)
3	Morcos, Paul A., "Gene switching: analyzing a broad range of mutations using steric block antisense oligonucleotides," Methods in Enzymology, Vol. 313:174-189 (1999)
4	MOULTON, H.M., "Compound and Method for Treating Myotonic Dystrophy," U.S. Application No. 12/493,140, 82 pages, filed June 26, 2009
5	MOULTON, Hong M. et al., "Morpholinos and their peptide conjugates: Therapeutic promise and challenge for Duchenne muscular dystrophy," Biochimica et Biophysica Acta, Vol. 1798:2296-2303 (2010)
6	Muntoni F, et al., "Dystrophin and mutations: one gene, several proteins, multiple phenotypes," Lancet Neurol. 2003;2:731-40.
7	MUNTONI, Francesco et al., "128th ENMC International Workshop on 'Preclinical optimization and Phase I/II Clinical Trials Using Antisense Oligonucleotides in Duchenne Muscular Dystrophy' 22-24 October 2004, Naarden, The Netherlands," Neuromuscular Disorders, Vol. 15:450-457 (2005) (Exhibit Number 2025 filed in interferences 106008, 106013, 106007 on November 18, 2014)
8	MUNTONI, Francesco et al., "149th ENMC International Workshop and 1st TREAT-NMD Workshop on: 'Planning Phase I/II Clinical trials using Systemically Delivered Antisense Oligonucleotides in Duchenne Muscular Dystrophy,'" Neuromuscular Disorders, Vol. 18:268-275 (2008)
9	Confirmatory Study of Eteplirsen in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsen in Duchenne Muscular Dystrophy, Clinical Trials.gov, Clinical Trial Identifier NCT02255552, May 26, 2015, 3 pages.
10	NELSON, David L. et al., "Nucleotides and Nucleic Acids," Lehninger Principles of Biochemistry, 3rd Edition, Chapter 10, pages 325-328 and glossary page G-11, Worth Publishers, New York (2000)
11	Nguyen TM, et. Al., "Use of Epitope libraries to identify exon-specific monoclonal antibodies for characterization of altered dystrophins in muscular dystrophy," Am J Hum Genet 1993;52:1057-66.

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12		Oberbauer, "Renal uptake of an 18-mer phosphorothioate oligonucleotide," Kidney Int'l, Vol. 48, pp. 1226-1232 (1995), Exhibit Number 1191 filed in Interferences 106,007 and 106,008 on February 17, 2015.
13		Oligonucleotide Cleavage and Deprotection Laboratory Notebook Entry, Pages 1, Exhibit Number 1138 filed in Interferences 106,007 and 106,008 on February 16, 2015.
14		Oligonucleotide diagrams, 5 pages (Exhibit Number 1053 filed in interferences 106008, 106007 on November 18, 2014)
15		Partial European Search Report for Application No. 10004274.6, 6 pages, dated October 2, 2012
16		Partial European Search Report for Application No. 12162995.0, 6 pages, dated October 2, 2012
17		Patentee's Response to European Patent Application No. 05076770.6, dated July 28, 2006, 4 pages
18		Patrick O. Brown and Tidear D. Shalon v. Stephen P.A. Fodor, Dennis W. Solas and William J. Dower: Interference Merits Panel, Interference No. 104,358, 24 pages, dated August 9, 1999 (Exhibit Number 2113 filed in interferences 106008, 106013, 106007 on November 18, 2014)
19		PCT Application as-filed for application No. PCT/NL03/00214, 64 pages, dated September 21, 2005 (Exhibit Number 2042 filed in interferences 106008, 106013, 106007 on November 18, 2014)
20		PD-10 Desalting Columns, Pages 12, Exhibit Number 1141 filed in Interferences 106,007 and 106,008 on February 16, 2015.
21		Popplewell, et al., Design of Phosphorodiamidate Morpholino Oligomers (PMOs) For the Induction of Exon Skipping of the Human DMD Gene, DSGT Poster, 2008, 1 page.
22		POPPLEWELL, Linda et al., "Design of phosphorodiamidate morpholino oligomers (PMOs) for the induction of exon skipping of the human DMD gene," Human Gene Therapy 19(10): ESGCT 2008 Poster Presentations, Page 1174, Poster No. P203

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23		POPPLEWELL, Linda J. et al., "Comparative analysis of antisense oligonucleotide sequences targeting exon 53 of the human DMD gene: Implications for future clinical trials," Neuromuscular Disorders, Vol. 20(2):102-110 (2010) 9 pages (Exhibit Number 2031 filed in interferences 106008, 106013, 106007 on November 18, 2014)
24		POPPLEWELL, Linda J. et al., "Design of Antisense Oligonucleotides for Exon Skipping of the Human Dystrophin Gene," Human Gene Therapy 19(4): BSGT 2008 Poster Presentation, Page 407, Poster No. P-35
25		POPPLEWELL, Linda J. et al., "Design of Phosphorodiamidate Morpholino Oligomers (PMOs) for the Induction of Exon Skipping of the Human DMD Gene," Molecular Therapy, Vol. 17(3):554-561 (2009)
26		POPPLEWELL, Linda J. et al., "Targeted Skipping of Exon 53 of the Human DMD Gene Recommendation of the Highly Efficient Antisense Oligonucleotide for Clinical Trial," Human Gene Therapy 20(4): BSGT 2009 Poster Presentations, Page 399, Poster No. P10
27		Poster Abstract Listing for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2137, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).
28		Pramono, "Induction of Exon Skipping of the Dystrophin Transcript in Lymphoblastoid Cells by Transfected an Antisense Oligodeoxynucleotide Complementary to an Exon Recognition Sequence," Biochem. and Biophys. Res. Comm., Vol. 226, pp. 445-449 (1996), Exhibit Number 1192 filed in Interferences 106,007 and 106,008 on February 17, 2015.
29		Preliminary Amendment for Application No. 12/976,381, 4 pages, dated December 22, 2010 (Exhibit Number 2066 filed in interferences 106008, 106013, 106007 on November 18, 2014)
30		Preliminary Amendment for Application No. 12/198,007, 3 pages, dated November 7, 2008 (Exhibit Number 2067 filed in interferences 106008, 106013, 106007 on November 18, 2014)
31		Prescribing Information for EXONDYS 51 (eteplirsen) Injection, dated 09/2016, 10 pages
32		Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
33		Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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34		Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.
35		Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
36		Raz et al. v. Davis et al., Board of Patent Appeals and Interferences, Patent and Trademark Office, Int. No. 105,712, Tech. Ctr. 1600, September 29, 2011 (24 pages) (2011 WL 4568986 (Bd.Pat.App. & Interf.), Exhibit Number 1209 filed in Interferences 106,007 and 106,008 on February 17, 2015.
37		REESE, Colin B. et al., "Reaction Between 1-Arenesulphonyl-3-Nitro-1,2,4-Triazoles and Nucleoside Base Residues. Elucidation of the Nature of Side-Reactions During Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 21:2265-2268 (1980)
38		REESE, Colin B. et al., "The Protection of Thymine and Guanine Residues in Oligodeoxyribonucleotide Synthesis," J. Chem. Soc. Perkin Trans. 1, pages 1263-1271 (1984)
39		Reexamination Certificate - Application No. 90/011,320, issued March 27, 2012 (Exhibit Number 1072 filed in Interferences 106008, 106007 on December 23, 2014)
40		Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
41		Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).
42		Reply to EPO Communication dated October 23, 2014 in European Application Serial No. 12198485, (University of Western Australia Exhibit 2147, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-8).
43		Response to Office Action and Amendments to the Claims for Application No. 13/550,210, 10 pages, dated May 12, 2014 (Exhibit Number 2064 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
44		Rhodes et al., "BioMarin Bulks Up," BioCentury, pp. 6-8 (December, 2014), Exhibit Number 1193 filed in Interferences 106,007 and 106,008 on February 17, 2015.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number <b>#. 30791</b>	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	RNA Isolation Using RNA-BEE, Pages 1, Exhibit Number 1175 filed in Interferences 106,007 and 106,008 on February 16, 2015.
46	ROBERTS, Roland G. et al., "Exon Structure of the Human Dystrophin Gene," Genomics, Vol. 16:536-538 (1993)
47	Roest et al., "Application of In Vitro Myo-Differentiation of Non-Muscle Cells to Enhance Gene Expression and Facilitate Analysis of Muscle Proteins," Neuromuscul. Disord., Vol. 6, No. 3, pp. 195-202 (May, 1996), Exhibit Number 1124 filed in interferences 106,007 and 106,008 on February 17, 2015.
48	ROSSO, Mario G. et al., "An Arabidopsis thaliana T-DNA mutagenized population (GABI-Kat) for flanking sequence tag-based reverse genetics," Plant Molecular Biology, Vol. 53:247-259 (2003)
49	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, Abstract [136] 1 page.
50	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, pages 1-11.

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Application Number <b>#. 30792</b>	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	30440717
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Amy E. Mandragouras/Anita Costa
<b>Filer Authorized By:</b>	Amy E. Mandragouras
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	22-SEP-2017
<b>Filing Date:</b>	
<b>Time Stamp:</b>	17:07:55
<b>Application Type:</b>	Utility under 35 USC 111(a)

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4	Information Disclosure Statement (IDS) Form (SB08)	SB5.pdf	1069449 ba40313de315f4dec1f9a32110c65ec35907 6243	no	8
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5	Information Disclosure Statement (IDS) Form (SB08)	SB10.pdf	1063176 c32eec39a978355c4f941c38025125cdf81b 8ba6	no	8
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6	Information Disclosure Statement (IDS) Form (SB08)	SB11.pdf	4828a2a56988fdff90d09c2e9ab956f9df562 0fb	no	8
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7	Information Disclosure Statement (IDS) Form (SB08)	SB12.pdf	1062574 d7e40a65a345f3325bbc488276dd67300e4 6c13c	no	8
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8	Information Disclosure Statement (IDS) Form (SB08)	SB13.pdf	1064319 6572b386755cb262b46428bd784fef13d70 ba156	no	8
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9	Other Reference-Patent/App/Search documents	11570691.pdf	824636 b1d71a5423cfcbdc747bca834f34371d79a4 41b4	no	20
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10	Other Reference-Patent/App/Search documents	12605276.pdf	3052455 6b079d4e84963b993a6d850b85dd7bf524 6a107e	no	77
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11	Other Reference-Patent/App/Search documents	12837356.pdf	7d5447617e4bddfd2424e1403dd112bb53 477bf6	no	27
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12	Other Reference-Patent/App/Search documents	12837359.pdf	1720784  39f2b87208fb3d32fd5dc8a05cf21c5f9c8793 e7c	no	43
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13	Other Reference-Patent/App/Search documents	12860078.pdf	330860  258ddd90a3313de714b6ffdd0f97951bbb7 b2241	no	5
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14	Other Reference-Patent/App/Search documents	13168857.pdf	328406  1b77d7a519c9b4966ebf7331ae532f95fb3 20bc	no	9
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15	Other Reference-Patent/App/Search documents	13168863.pdf	953673  75890e005398e8da1561538cd7f5edc5d4d 26aff	no	23
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16	Other Reference-Patent/App/Search documents	13270500.pdf	1518462  d4b14d0d1ce4e349ab743a0c3ab1daba78 e57fcf	no	37
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17	Other Reference-Patent/App/Search documents	13270531.pdf	661676  a34a8a8703fa12c091a1195daba43351c7bf f0c0	no	18
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18	Other Reference-Patent/App/Search documents	13270744.pdf	1198792 d9311801bf221c828547edf308cab084161 ebf0d	no	28
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19	Other Reference-Patent/App/Search documents	13270937.pdf	1201425 82d5399512674134bc8354b842dbf7cb112 6bf17	no	30
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20	Other Reference-Patent/App/Search documents	13270992.pdf	1429782 54349a132fa1bda28ef37405a23d6006b7a c2211	no	37
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21	Other Reference-Patent/App/Search documents	13271080.pdf	1180426 c629f772d342b4fce726c39e0a00921f647f 0de	no	30
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22	Other Reference-Patent/App/Search documents	13509331.pdf	620522 0a679286a4d1346b914b57539955f747269 c8c3a	no	13
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23	Other Reference-Patent/App/Search documents	13727415.pdf	341405 cf41e336c31931d38290ae5411453722cb4 0ba10	no	9
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24	Other Reference-Patent/App/Search documents	13741150.pdf	1312837 56cfe4fcfce3533db328d5fa8b340bdd2114 a0bc	no	26
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25	Other Reference-Patent/App/Search documents	13826613.pdf	ae217f3bc5ff1d7f5c751796c547132a5fe1 792	no	19
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26	Other Reference-Patent/App/Search documents	13826880.pdf	1289334  c090a0236018fbae6b5cf3ad0c020628ba2c 6860	no	26
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27	Other Reference-Patent/App/Search documents	13829545.pdf	391313  9644b3c4b1cb8009fdbfb01b8884260e3cc8f a1a6	no	10
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28	Other Reference-Patent/App/Search documents	13830253.pdf	769195  1242fc1883343a669dafecae08c8a3f885f7e c20	no	16
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29	Other Reference-Patent/App/Search documents	13902376.pdf	1290892  2bbf2ddbc5cb8c89a2343f26803153ea0d 14001	no	32
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30	Other Reference-Patent/App/Search documents	13963578.pdf	403329  3402d75f53e3d4cac07805b91e3b53a992e 0df43	no	10
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31	Other Reference-Patent/App/Search documents	14086859.pdf	647296  c11ab966c5b0d9558867e77e9f02adefef0 d7620	no	15
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32	Other Reference-Patent/App/Search documents	14108137.pdf	5b48582097de7e4dd0951dc9431cf45c901 7ff61	no	18
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33	Other Reference-Patent/App/Search documents	14178059.pdf	373078  51fd4e3376bcfce4152ebdd82c80ae43ef14 9b7b	no	8
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34	Other Reference-Patent/App/Search documents	14213607.pdf	1153046  a5d85ac9c07d17a054ac70b0d7ee10d6377 79599	no	25
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35	Other Reference-Patent/App/Search documents	14213629.pdf	917107  ebdce12777edce60358255530c44892d0e6 12630	no	23
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36	Other Reference-Patent/App/Search documents	14213641.pdf	5407199  e3e4a1984127ea855fd2b947c1e3b8e68ee 502b9	no	125
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37	Other Reference-Patent/App/Search documents	14214480.pdf	5531647  47769b062d112ad0a371db384865d858b9 17fec	no	129
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38	Other Reference-Patent/App/Search documents	14214567.pdf	947976  bcc4df502112e0e4fb29c60d2df807db82b10 b702	no	21
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39	Other Reference-Patent/App/Search documents	14223634.pdf	d2ad35987905441de8b67a24adaac5c6f27 4a20f	no	9
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**Warnings:****Information:**

40	Other Reference-Patent/App/Search documents	14273318.pdf	1069737  19250769e0a95a5359c4bb08b99e392fd92 ee5d7	no	27
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41	Other Reference-Patent/App/Search documents	14273379.pdf	779288  d1bee3a17b36cf262546affd551f529a7f60 ea8	no	17
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42	Other Reference-Patent/App/Search documents	14316603.pdf	895109  d45947c6797378a6b1d11b20e3ac2a95fb8 0a96d	no	21
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43	Other Reference-Patent/App/Search documents	14316609.pdf	1048531  44030b7a819393f479c49ef9e8b01ea2665 aedd	no	23
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44	Other Reference-Patent/App/Search documents	14317952.pdf	706351  463631f0235c23f3a173d5744266a0e5faaf5 655	no	14
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45	Other Reference-Patent/App/Search documents	14523610.pdf	1213794  b225eac5cfbebf4a1536faf87bcb61f5d2570 153	no	30
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46	Other Reference-Patent/App/Search documents	14740097.pdf	0989f8e4794f9e7a0ae034ce1ab616471673 78a3	no	19
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47	Other Reference-Patent/App/Search documents	14743856.pdf	320959  71b8543c73fef28cc3085fc6622449de71f27 7dc	no	9
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48	Other Reference-Patent/App/Search documents	14776533.pdf	846911  8bddf6142074e45a53bb5dd05c2afc8d63 5c22d	no	21
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49	Other Reference-Patent/App/Search documents	14852090.pdf	954681  c549f53d97cb070417db369d7bc58f9e730 eeda0	no	18
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50	Other Reference-Patent/App/Search documents	14852149.pdf	361683  757eee3cd8596e225527cbaec402c34f1cb5 6649	no	6
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51	Other Reference-Patent/App/Search documents	14852257.pdf	749921  44d935fd370e4f76d918d9d599634b53611 b345a	no	11
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**Warnings:****Information:**

52	Other Reference-Patent/App/Search documents	14852264.pdf	816621  c048541fdf6765ca96797c2bf12dcc04b831f dd2	no	17
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**Warnings:****Information:**

53	Other Reference-Patent/App/Search documents	14857555.pdf	0a94c12f5b3cf7bc09416e8ab245c525fb76 0cd1	no	12
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54	Information Disclosure Statement (IDS) Form (SB08)	IDSTRANS.pdf	50276  13a3bdfb712873269000ce5571df1d4f77d b5354	no	8
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55	Information Disclosure Statement (IDS) Form (SB08)	SB6.pdf	1089106  199adb629310f6e9470334515fb6536ab38 36165	no	8
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56	Information Disclosure Statement (IDS) Form (SB08)	SB8.pdf	1070179  d1cecb9ee54521a53c75ac10079b8920ed 80df8	no	8
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57	Information Disclosure Statement (IDS) Form (SB08)	SB9.pdf	1082063  2266dc70cc1a16858c72d12c6964c64eb87 988ad	no	8
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58	Information Disclosure Statement (IDS) Form (SB08)	SB14.pdf	1a7b1bb58e7ccb0ac8675a762dfe4863952 e4bac	no	8
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59	Information Disclosure Statement (IDS) Form (SB08)	SB1.pdf	1243016 5578a6b8352de19781eab64a3543a16fc87 6130a	no	32
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60	Information Disclosure Statement (IDS) Form (SB08)	SB7.pdf	1102078 876c1d3a049c64e4d8f3c7b1e4fdb52f3a2 4895	no	8
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE RECD	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/705,172	09/14/2017	1674	730	AVN-008CN41	2	2

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123147

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One Post Office Square  
Boston, MA 02109

FILING RECEIPT



CC000000094308384

Date Mailed: 09/26/2017

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Power of Attorney: The patent practitioners associated with Customer Number 123147

Domestic Priority data as claimed by applicant

This application is a CON of 15/274,772 09/23/2016  
which is a CON of 14/740,097 06/15/2015 PAT 9605262  
which is a CON of 13/741,150 01/14/2013 ABN  
which is a CON of 13/168,857 06/24/2011 ABN  
which is a CON of 12/837,359 07/15/2010 PAT 8232384  
which is a CON of 11/570,691 01/15/2008 PAT 7807816  
which is a 371 of PCT/AU2005/000943 06/28/2005

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**Projected Publication Date:** 01/04/2018

**Non-Publication Request:** No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***

**Title**

ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE  
THEREOF

**Preliminary Class**

536

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:** No

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